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Matt Hellman

Professor Hutt

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Commercial Drug Claims, The FDA, and the First Amendment

Introduction

Food and drug law has never sat comfortably with the bulk of the commercial speech doctrine. While general commercial speech doctrine has progressed from relatively humble beginnings¹ to a more esteemed place in the First Amendment pantheon,² food and drug speech has lagged behind.³ In recent years, however, courts, if not the FDA, have shown an increased willingness to afford food and drug manufacturers protection under the First Amendment. While the FDA has resolutely opposed any incursion on its ability to regulate the claims of pharmaceutical companies and dietary supplement manufacturers, those businesses have had some success in the courts, allowing them to articulate nonmisleading claims regardless whether the FDA has approved them. The importance of the issue is obvious, with both sides claiming that it is a matter not just of First Amendment doctrine, but of life and death. The manufacturers argue that without the ability to advertise their products, doctors and consumers will be denied the benefit of using them.⁴ Conversely, the FDA argues that consumers will be at risk unless it has complete authority to regulate the claims that the manufacturers make.⁵

¹See, e.g., *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 749 – 52 (1976).

²See, e.g., *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996).

³See, e.g., *United States v. Articles of Drug* 32 F.R.D. 32 (S.D. Il. 1963).

⁴See, e.g., Washington Legal Foundation, *Citizen Petition Regarding Dissemination of Non-Misleading Information Concerning Off-Label Uses of FDA-Approved Products*, *4 - *5, (May 23, 2001).

⁵See *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d. 51 (discussing FDA's concerns) (1998).

In two strands of what can only be described as extremely protracted litigation,⁶ the courts have begun to articulate a framework by which to evaluate these competing claims. Although the doctrine is hardly settled,⁷ in two lines of cases, *Washington Legal Foundation v. Friedman*⁸ and *Pearson v. Shalala*,⁹ courts have shifted the doctrine from requiring a unilateral ban on non-FDA approved advertising to a regime in which manufacturers of drugs and dietary supplements have more freedom to publicize their products, so long as they are accompanied with appropriate disclaimers. I argue in this paper that while this more nuanced approach is surely an improvement over the FDA's adamant refusal to acknowledge any First Amendment protection for these claims, it is still not entirely clear how much protection these claims should deserve in the face of public safety concerns. Because courts have not fully considered these countervailing concerns in granting First Amendment protections we must wait for a fully articulated and justifiable framework for weighing the speech interests in these cases against the interest of public safety.

This paper proceeds in four parts. Part I provides an overview of commercial speech doctrine, tracing the doctrine's development from an early period of disfavor to the more privileged status that it enjoys today. In particular, Part I traces the development of the important *Central Hudson* test which the courts have used to gauge the weight of the speech interest in the drug speech cases that form the heart of this paper. Part II turns to the food and drug context specifically and surveys some of the early cases in which the FDA was given extraordinarily free rein to restrict commercial drug speech. Part II also discusses some of the important statutory developments that have affected recent litigation. Part III introduces the two important recent lines of cases that have marked a turning point in commercial speech doctrine with respect to commercial drug speech. In *Washington Legal Foundation v. Friedman* the courts loosened

⁶Telephone Interview with Richard A. Samp, General Counsel, Washington Legal Foundation (describing the litigation as "protracted") (June 4, 2001).

⁷See *Washington Legal Foundation v. Henney*, 128 F.Supp.2d 11, 15 ("After six years' worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved, and the country's drug manufacturers are still without clear guidance as to their permissible conduct.") (D.D.C. 2000).

⁸*Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d. 51 (1998).

⁹*Pearson v. Shalala*, 164 F.3d 650, 654 (1999)

the restrictions on drug manufacturers, giving them greater freedom to publicize non-FDA approved uses of pharmaceuticals to doctors, so long as they provide a disclaimer about such uses. And in *Pearson v. Shalala*, the court permitted manufacturers to present truthful nonmisleading claims regarding the efficacy of dietary supplements even if the FDA had not verified the claims itself. In Part IV, I critique the decisions, applauding the courts for providing protection for these claims where the FDA had previously refused to grant it, but asking whether all of the assumptions that the courts employ in the cases are persuasive. I conclude that although an outright ban on the speech is unjustifiable, there may be relevant factors in particular instances that the opinions did not consider that would be sufficient to cause the public's interest in safety to trump its interest in speech.

Part I: First Amendment Protection for General Commercial Speech

This section traces the history of commercial speech under the First Amendment on its rocky course from its inauspicious beginnings to the more respected place in First Amendment jurisprudence that it now occupies.¹⁰ The story of the modern commercial speech doctrine begins with the seminal yet relatively vague case of *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*.¹¹ *Virginia Board* involved a Virginia statute that made advertising the prices of prescription drugs “unprofessional conduct” and that

¹⁰It is worth noting at the outset that it is one of the peculiarities of food and drug law that its First Amendment jurisprudence has not tracked particularly closely the history of the general commercial speech doctrine. See below at Part III for a discussion of the divergences between the two.

¹¹425 U.S. 748, 749 – 52 (1976).

imposed penalties of license suspension or revocation upon pharmacists who violated it.¹² Framing the question as whether a pharmacist who has no “wish to editorialize on any subject cultural, philosophical, or political,” nevertheless has a First Amendment right to advertise, the Court, per Justice Blackmun, stated that “speech does not lose its First Amendment protection because money is spent to project it, as in a paid advertisement of one form or another.”¹³

Justice Blackmun then cited several reasons why the pharmacist’s speech was deserving of at least some First Amendment protection. First, Justice Blackmun noted that the economic nature of the transaction could not be an absolute bar to such protection because the Court had accorded such protection to union members in labor disputes, in which the subject of the speech and the interest of the speakers are “primarily economic.”¹⁴ Second, Justice Blackmun stressed the fact that unlike many other types of speech, the value of commercial speech stems mainly from the needs of the listener rather than those of the speaker, and as such, he argued that the advertising speech should be protected because the suppression of drug prices “hits... hardest... the poor, the sick, and particularly the aged” who may have no other way of comparing pharmaceutical prices.¹⁵ Third, the Court pointed to an economic justification for striking down the ban on advertising: “So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable.”¹⁶

¹²*Id.* at 749 – 52 (1976).

¹³*Id.* at 761 (citing *Buckley v. Valeo*, 424 U.S. 1, 35 – 59 (1976); *New York Times Co.*, 376 U.S. at 266). *See also id.* at 762 (finding that speech “which does ‘no more than propose a commercial transaction’ is [not] so removed from any ‘exposition of ideas’... that it lacks all protection.” (citations omitted)).

¹⁴*Id.* at 762 (citing *NLRB v. Gisel Packing Co.*, 395 U.S. 575, 617 – 618 (1969); *NLRB v. Virginia Electric & Power Co.*, 314 U.S. 469, 477 (1941)).

¹⁵*Id.* at 763. It was undisputed that under the advertising ban enormous variations existed in the price of pharmaceuticals, even between stores in the same city. *Id.* at 754 (“It is stipulated, for example,... that in the Newport News-Hampton area, the cost of tetracycline ranges from \$1.20 to \$9.00, a difference of 650%.”).

¹⁶*Id.* at 765 (citing *Dun v. Bradstreet, Inc. v. Grove*, 404 U.S. 898, 904 – 06 (1971) (Douglas, J., dissenting from denial of certiorari); *FTC v. Proctor & Gamble Co.*, 386 U.S. 568, 603 – 04 (1967) (Harlan, J., concurring)).

Based upon these rationales, Justice Blackmun concluded that commercial speech was deserving of some protection, although he declined to specify precisely the level of protection.¹⁷ Thus, other than a brief mention in passing of the fact that “[u]ntruthful speech, commercial or otherwise, has never been protected for its own sake,”¹⁸ further elaboration of the extent of the government’s right to restrict commercial speech remained lacking until *Central Hudson Gas & Electricity Corp. v. Public Service Commission*, decided six years later.¹⁹ *Central Hudson* articulated the framework that is still used today for determining the constitutionality of government regulation of commercial speech. The case concerned a state regulation forbidding advertisement by power companies to promote the use of electric power.²⁰ In striking down the advertisement ban as unconstitutional under the First and Fourteenth Amendments,²¹ the Court noted a tension between its “reject[ion of] the highly paternalistic view that government has complete power to suppress or regulate commercial speech”²² and “the ‘commonsense’ distinction between speech proposing a commercial transaction that occurs in an area traditionally subject to government regulation, and other varieties of speech.”²³

To resolve this conflict, the Court specified a four-part test to gauge the constitutionality of the regulation on speech in question. First, if the communication in question is “neither misleading nor related to unlawful activity, the government’s power is more circumscribed.”²⁴ Second, the Court stated that such regulations

¹⁷*Id.* at 770. (“In concluding that commercial speech, like other varieties, is protected, we of course do not hold that it can never be regulated in any way.”).

¹⁸*Id.* at 771 (citing *Gertz v. Robert Welch Inc.*, 418 U.S. 323, 340 (1974)).

¹⁹447 U.S. 557 (1980). One relatively important commercial speech case was handed down in the interim between *Virginia Pharmacy* and *Central Hudson*. In *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447 (1978), the Court upheld the application of a “prophylactic” rule providing for the indefinite suspension of attorneys who recommend themselves to potential clients who had not sought their services. *Id.* at 449. Although the Court recognized that *Virginia Pharmacy* granted some First Amendment protection to commercial speech, *id.* at 457, it concluded that “the entitlement of in-person solicitation to the protection of the First Amendment [was different in the present situation, as was] the strength of the State’s countervailing interest in prohibition.” *Id.* at 455. *Ohralik* was employed unsuccessfully by the FDA in attempting to justify regulations on continuing medical education programs and reprint distributions to physicians. See *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d. 51, 60 (1998). For a discussion of the FDA’s arguments in *Washington Legal Foundation*, see below at Part III.

²⁰*Cent. Hudson Gas & Elect. Corp.*, 447 U.S. at 559.

²¹See *id.* at 566 – 571.

²²*Id.* at 562 (internal quotation marks omitted) (citing *Virginia Pharmacy Board*, 425 U.S. at 770).

²³*Id.* (quoting *Ohralik*, 436 U.S. at 455 – 56).

²⁴*Id.* at 564.

would receive a form of intermediate scrutiny, such that “[t]he State must assert a substantial interest to be achieved by restrictions on commercial speech.”²⁵ Third, the regulation must “directly advance the state interest involved;”²⁶ and fourth, there must not be “a more limited restriction on commercial speech” that could serve the government’s interest equally well.²⁷

Although this four-part test ostensibly filled out the relatively vague holding of *Virginia Pharmacy*, its has proven to be somewhat difficult to apply in practice and has been used both to uphold and strike down similar restrictions on commercial speech. For example, in *Posadas de Puerto Rico Associates v. Tourism Co.*,²⁸ a decision that perhaps represents the low point of general commercial speech protection post-*Virginia Pharmacy*, the Court employed the *Central Hudson* test in upholding a ban on the advertisement of casino gambling.²⁹ Noting at the outset that casino gambling was not an illegal activity and that the advertisement of it was neither misleading nor fraudulent, the Court turned to the other prongs of the test.³⁰ In evaluating the second prong, the Court gave great deference to the findings of the Puerto Rican legislature, and concluded that it “ha[d] no difficulty in concluding that the... Legislature’s interest in the health, safety, and welfare of its citizens constitutes a substantial government interest.”³¹ The Court was similarly swayed by Puerto Rico’s arguments that the advertising ban would directly advance the government’s interest in the well-being of its citizens³² and that the ban was sufficiently narrowly-tailored to effectuate this interest.³³

²⁵*Id.*

²⁶*Id.*

²⁷*Id.* This last prong of the *Central Hudson* test has been elaborated upon the most in the intervening years. In *Board of Trustees of the State University of N.Y. v. Fox*, 492 U.S. 469 (1989), the Court stated that although the *Central Hudson* test speaks of a requirement that the restriction be “no more extensive than necessary,” *Cent. Hudson Gas & Elec.*, 447 U.S. at 569 – 70, the term should be understood more loosely than is literally implied by the word “necessary.” *Fox*, 492 U.S. at 476 – 77 (citing *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 411 – 25 (1819) (discussing the various possible meanings of the word “necessary”) and *In re R. M. J.*, 455 U.S. 191, 203 (1982) (employing the *Central Hudson* test but merely requiring that the restrictions in question be “narrowly drawn”)). As such, the Court has transformed the “brightline” rule quality of the fourth prong as articulated in *Central Hudson* into a more flexible (and pro-government) standard that only requires that the restriction be “narrowly tailored.” *Id.* at 477 – 79.

²⁸478 U.S. 328 (1986).

²⁹*Id.* at 331.

³⁰*Id.* at 340.

³¹*Id.* at 341 (quotation marks omitted) (citing authority).

³²*Id.* at 341 – 42.

³³*Id.* at 343 – 44.

Although the appellant casino company maintained that the ban was underinclusive because it did not prohibit the advertisement of other forms of gambling,³⁴ and that a complete advertising ban was more extensive than was necessary because the proper remedy under the First Amendment required the promulgation of speech discouraging gambling rather than the banning of advertising encouraging it, the Court was unmoved by both of these propositions.³⁵ Thus, with its heavy deference to government findings, *Posadas* represents one of the more lenient applications of the *Central Hudson* test.

On the other side of the spectrum lies 44 *Liquormart, Inc. v. Rhode Island*,³⁶ which perhaps provides a more accurate statement of the Court's current commercial speech jurisprudence. *Liquormart* concerned another wholesale ban on advertising, in this instance a ban on advertisements stating the price of liquor. Although the government advanced the same rationales pertaining to the health and welfare of its citizens as in *Posadas*,³⁷ the Court proved far less receptive to the arguments. Working from the premise that advertising "bans that target truthful, nonmisleading commercial messages... often serve only to obscure an underlying governmental policy that could be implemented without regulating speech... [and thus] impede debate over central issues of public policy,"³⁸ the Court, per Justice Stevens, found that the ban did not "significantly advance the State's interest in promoting temperance."³⁹ Although Justice Stevens recognized that the ban "may have some impact on the purchasing patterns of temperate drinkers of moderate

³⁴*Id.* at 342.

³⁵*Id.* at 344. The Court found the regulation to be sufficiently narrowly-tailored because it only banned casino advertisements in the local Puerto Rico media. *Id.* at 343 – 44. Thus, according to the Court, the regulations allowed the promotion of the casino industry to tourists, while allowing the government to further its interest in maintaining the welfare of its citizens. *Id.*

³⁶517 U.S. 484 (1996).

³⁷*Id.* at 504 ("The State argues that the price advertising prohibition should nevertheless be upheld because it directly advances the State's substantial interest in promoting temperance...."). See also *id.* at 508 ("The State [argues] that it merely exercised appropriate 'legislative judgment' in determining that a price advertising ban would best promote temperance."). Rhode Island did advance a novel rationale for the ban beyond simply arguing that a ban on price advertising would make directly decrease consumer demand for alcohol: it also posited a supply side effect through which the advertising ban would mitigate competition, thus allowing competitors to charge more for their product and in turn reducing the amount purchased. *Id.* at 505.

³⁸*Id.* at 503 (footnote and internal quotation marks omitted) (quoting *Central Hudson*, 447 U.S. at 566 n.9) (citing *Central Hudson*, 447 U.S. at 575 (Blackmun, J., concurring in judgment)).

³⁹*Id.* at 505.

means,”⁴⁰ he argued that any claim that lifting the ban “would significantly increase alcohol consumption” would constitute the type of speculation that “certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends.”⁴¹

The Court focused on the same paternalism concerns in concluding that the advertising ban was more extensive than necessary. Although Rhode Island relied upon *Posadas* in arguing that its legislative judgment regarding the appropriateness of the ban should be respected,⁴² Justice Stevens contended that *Posadas* had been wrongly decided and that contrary to the decision in that case, it was not “up to the legislature to choose suppression over a less speech-restrictive policy.”⁴³ Thus, *Liquormart* represents a particularly anti-paternalistic decision in which the Court deemed a complete ban on information to be too blunt an instrument to justify the state’s interests. To the extent it represents the Court’s current thinking on First Amendment protection of commercial speech, *Liquormart*’s vision of consumers who are capable of placing information in context and making informed decisions suggests that less regulation may be appropriate in the food and drug context.⁴⁴ It is this context that forms the focus of the rest of this paper.

Part II: Food and Drug Speech and the First Amendment

A.. *Early Food and Drug Speech Cases*

Food and drug speech, although ostensibly under the purview of First Amendment commercial speech jurisprudence, has not generally been accorded the same protections as other forms of commercial speech.

⁴⁰*Id.* at 506.

⁴¹*Id.* at 507 (citing authority).

⁴²*Id.* at 508.

⁴³*Id.* at 509 (internal quotation marks omitted). This portion of the opinion only secured the votes of four Justices: Justices Stevens, Kennedy, Thomas, and Ginsburg.

⁴⁴See Margaret Gilhooley, *Constitutionalizing Food and Drug Law*, 74 TUL. L. REV. 815, 859 (2000) (discussing the implications of the *Liquormart* decision for food and drug law).

Indeed, the courts have generally treated food and drug regulations quite gingerly. Stretching back to *United States v. Carolene Products Co.*,⁴⁵ the famous 1938 case in which the Court upheld a ban on the interstate shipment of filled milk by employing rational basis review,⁴⁶ legislative judgments regarding what is “injurious to the public health” have been given great leeway.⁴⁷

With respect to the First Amendment in particular, speech that would likely otherwise have received protection in different commercial contexts has been treated with a special solicitude by the courts. For example, in *United States v. Articles of Drug*,⁴⁸ a district court upheld the seizure of a nutrition book that was displayed (unbeknown to the author) near certain vitamins and that contained information the FDA considered to be inaccurate.⁴⁹ Even though the author did not intend for the book to be marketed with the vitamins, the FDA was able to argue successfully that the book was part of the vitamin’s labeling, and thus constituted a misbranding violation under the Federal Food, Drug, and Cosmetic Act (FD&C Act).⁵⁰

In response to the author’s claims that the seizure violated his First Amendment rights, the court offered little insight into its analysis, noting only that the Act “prohibits false labeling and misbranding, and authorizes the seizure of [such] articles,” and that any First Amendment concerns were mitigated by the fact that “the condemnation... could not operation as a restraint upon the sale of the book through book stores or other outlets.”⁵¹ Even leaving aside the fact that the book might not properly even be considered commercial speech because its primary purpose was not to facilitate an economic transaction but to express an opinion, thus giving it full protection under the First Amendment, the court apparently found the commercial speech implications of the decision to be sufficiently uncontroversial to merit little analysis.

⁴⁵304 U.S. 144 (1938).

⁴⁶*Id.* at 152 & n.4.

⁴⁷*Id.* at 147 (citing authority).

⁴⁸32 F.R.D. 32 (S.D. Ill. 1963).

⁴⁹*Id.* at 33 – 34.

⁵⁰21 U.S.C. § 343 (1994).

⁵¹*Articles of Drug*, 32 F.R.D. at 35 (citing *United States v. 8 Cartons, etc., Molasses*, 103 F.Supp. 626 (W.D.N.Y. 1951)).

B. NLEA

Although the commercial speech implications of *Articles of Drug* are provocative, much of the debate about the extent of First Amendment protection for food and drug commercial speech has focused on the implications of two recent amendments to the FD&C Act: the Nutrition Labeling and Education Act of 1990 (NLEA),⁵² the Dietary Supplement Health and Education of 1994 (DSHEA),⁵³ as well as two guidance documents promulgated by the FDA concerning speech restrictions on continuing medical education seminars⁵⁴ and distributions of reprints of studies of off-label uses of drugs.⁵⁵ Congress passed the NLEA in light of the FDA's attempt to deal with food manufacturers that wished to make health claims about their products.⁵⁶ Beginning in 1984, when the Kellogg Company, with the approval of the National Cancer Institute, included on the label of its All-Bran cereal the claim that fiber had been shown to reduce the risk of colon cancer, the FDA has been forced to consider whether it would allow such claims in the absence of its own testing.⁵⁷ At the time, although the FDA had allowed food manufacturers to make a limited number of so-called "structure-function" claims for their products without subjecting them to the more onerous regulations for drugs,⁵⁸ it forbade health claims stating that a food would have an ameliorative effect upon a disease.⁵⁹ In 1990, after the FDA had promulgated a series of regulations and drafted others that had gradually increased the claims available to manufacturers, Congress passed the NLEA, allowing the FDA to pre-approve health claims by food manufacturers when "the Secretary determines, based on the totality of publicly available scientific evidence... , that there is significant scientific agreement, among [qualified] experts... , that the

⁵²Pub. L. No. 101-535, 104 Stat. 2553 (codified at 21 U.S.C. § 301 (1994)).

⁵³Pub. L. No. 103-417, 108 Stat. 4325 (codified in scattered sections of 21 U.S.C.; 42 U.S.C. (1994)).

⁵⁴Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed.Reg. 64074 (1997).

⁵⁵Advertising and Promotion; Guidances, 61 Fed.Reg. 52800 (1996).

⁵⁶See Steven B. Steinborn & Kyra A. Todd, *The End of Paternalism: A New Approach to Food Labeling*, 54 FOOD DRUG L.J. 401, 404 (1999).

⁵⁷*Id.*

⁵⁸An example of an acceptable structure-function claim is "Calcium builds strong teeth." *Id.*

⁵⁹Thus, the All-Bran claim was technically unacceptable under the FDA's policy at the time. Kellogg, however never faced action by the FDA as a result of extenuating political factors. *Id.*

claim is supported by such evidence.”⁶⁰ The FDA, however, has proven reluctant to authorize these claims, having only allowed ten of them since the passage of the NLEA.⁶¹ As a result, the NLEA has proven to be less than a wholly effective vehicle for manufacturers who wish to make health claims about their product.

C. DSHEA

Although the NLEA promulgated standards for health claims pertaining to foods, Congress chose to allow the FDA to determine its own regulations concerning health claims made regarding dietary supplements.⁶² In order to avoid confusion, the FDA adopted the same standards for dietary supplement health claims that Congress had authorized for food health claims.⁶³ Similar to its treatment of food health claims, the FDA only authorized one dietary supplement health claim.⁶⁴ In response to industry concerns that the FDA was not moving quickly enough to authorize health claims for dietary supplements,⁶⁵ Congress passed the DSHEA in 1994. The provision of DSHEA containing the most important First Amendment implications is §343-2(a), which allows manufacturers and retailers to make truthful and non-misleading health claims that have not been pre-approved by the FDA, so long as the claims are made only on accompanying products (for example, reprints of articles touting the dietary supplement) and not on the dietary supplement itself.⁶⁶ Although

⁶⁰§ 343(r)(3)(B)(1) (1994) (“A regulation [approving a health claim] shall describe the relationship between a nutrient... and a disease or health-related condition.”)

⁶¹21 C.F.R. §§ 101.72 – 81 (1999) (allowing such health claims as those based on the relationship between “[f]olate and neural tube defects”); *see also* Steinborn & Todd, *supra* note 56, at 406 (noting the relative lack of claims allowed by the FDA under the NLEA).

⁶²§ 343(r)(5)(D) (“A [health] claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances... shall be subject to a procedure and a standard, respecting the validity of such claim, established by regulation of the Secretary.”)

⁶³59 Fed. Reg. 395, 425 (1994).

⁶⁴Laura A. W. Khatcheressian, *Regulation Of Dietary Supplements: Five Years Of DSHEA*, 54 FOOD DRUG L.J. 623, 625 (1999).

⁶⁵*See* Peter A. Vignulo, Note, *The Herbal Street Drug Crisis: An Examination Of The Dietary Supplement Health And Education Act Of 1994*, 21 SETON HALL LEGIS J. 204 (1997). The DSHEA was actually Congress’s second post-NLEA attempt to encourage the FDA to allow a greater number of dietary supplement health claims. Two years after the enactment of the NLEA, Congress passed a one-year moratorium on its application to dietary supplements. *See* Prescription Drug User Fee Act, Pub. L. No. 102-571, 106 Stat. 4491 (codified in scattered sections of 21 U.S.C. et seq.).

⁶⁶21 § 343-2(a). The DSHEA also shifted the burden of proof from the manufacturer to the government in proving that any such external information is misleading. 21 U.S.C. 343-2(c).

the importance of these reforms to dietary supplement manufacturers should not be understated in light of cases like *United States v. Articles of Drug*, DSHEA did not change the requirements that manufacturers face in obtaining FDA approval for health claims on the product itself. It is these requirements that formed the basis of the litigation in *Pearson v. Shalala*.⁶⁷

D. Guidance Documents

The FDA has also promulgated two recent guidance documents concerning the relationship between commercial speech and drugs that have proved a fertile source of commercial speech litigation. The first of these documents lays out the requirements for continuing medical education programs. These programs serve as seminars for physicians in which they may learn about the latest research regarding given drugs. Because physicians are allowed to prescribe FDA-approved drugs for unapproved uses,⁶⁸ the FDA has been concerned that drug manufacturers would use these CME programs to advertise and promote off-label (i.e., non-FDA-approved) uses of their products. As such, the agency developed a series of rules to ensure a sufficient degree of separation between the manufacturers of the drug and the sponsors of the program. The FDA considers several factors in evaluating the independence of the CME program, including who chooses the moderator, content and presenters, the relationship between the supporting companies and the CME provider, and the degree of opportunity for open discussion about the ideas presented.⁶⁹

Another source of concern for the FDA stems from the use by drug manufacturers of reprints of studies showing the efficacy of their drugs for off-label uses. On one hand, given that in many areas of medicine a significant percentage of drugs are prescribed by physicians for off-label purposes, drug manufacturers have an economic incentive to inform physicians of studies that demonstrate the possibility of these new off-label

⁶⁷See *infra* Part III.

⁶⁸See, e.g., 59 Fed.Reg. 59820, 59821 (1994) (noting that the agency has restated this policy on numerous occasions).

⁶⁹See 62 Fed. Reg. 64088 – 99.

uses. On the other, the FDA requires a rigorous pre-approval process for on-label uses to determine their safety, thus if manufacturers may publicize off-label uses by sending reprints of reports directly to physicians, they will have no incentive to seek on-label approval. As a result, the FDA strictly regulates the communications between manufacturers and physicians, requiring that all reprinted reports focus primarily on FDA-approved uses of the drug and that they include the original study that led to FDA approval of the drug.⁷⁰

These two categories of restrictions, the NLEA/DSHEA regulations concerning dietary supplement health claims, and the FDA regulations pertaining to manufacturer-physician relations in the context of CME seminars and reprints, have been the basis of the most important recent commercial speech cases in food and drug law: *Washington Legal Foundation v. Friedman* and *Pearson v. Shalala*. The remainder of this paper is concerned with the analysis of these cases.

Part III: Recent Food and Drug Law Commercial Speech Cases

A. *Manufacturer – Physician Commercial Speech: Washington Legal Foundation v. Friedman*

Washington Legal Foundation v. Friedman, along with the subsequent litigation that arose from it,⁷¹ represents a major curtailment of the FDA’s ability to regulate manufacturer – physician commercial speech. The case, which was brought by a nonprofit interest group on behalf of several pharmaceutical manufacturers,⁷² concerned the extent to which the FDA could regulate commercial speech in the reprint and CME contexts. In particular, the plaintiff challenged the provisions of the guidance documents requiring that the reprinted

⁷⁰See 61 Fed. Reg. 52801 (1996).

⁷¹See *infra* note 95.

⁷²*Washington Legal Foundation*, 13 F.Supp.2d. 51, 54 (1998).

material and CME seminars contain some information about FDA-approved uses for the drug.⁷³ In an opinion that placed heavy weight on First Amendment protections, the court granted summary judgment to the plaintiff, enjoining the FDA from enforcing its guidance documents in such way as to require on-label descriptions.⁷⁴

After reviewing the guidance documents in question, the court began by considering what analytical framework would be appropriate to analyze the plaintiff's claims. Dispensing quickly with the FDA's claims that the behavior in question was not speech but conduct,⁷⁵ and, in the alternative, that any speech element involved would not merit First Amendment protection because the drug industry was already extensively regulated,⁷⁶ the court turned to the question whether the speech should be understood as commercial or pure speech. Here, the court sided with the FDA, finding the speech to be commercial speech despite the fact that it contained a "complex mixtures of commercial and non-commercial elements."⁷⁷ Accepting the proposition that it is "beyond dispute that when considered outside of the context of manufacturer promotion of their drug products, CME seminars, peer-reviewed medical journal articles and commercially-available medical textbooks merit the highest degree of constitutional protection,"⁷⁸ the court nevertheless determined that the economic motivation of the speakers was sufficiently strong to mandate classifying the speech under the

⁷³*Id.* at 57 – 58.

⁷⁴*Id.* at 74 – 75.

⁷⁵*Id.* at 59 – 60. The court appeared to have little patience for the FDA's argument that the distribution of reprints and the organization of seminars were not speech. "[T]he activities at issue in this case are only 'conduct' to the extent that moving one's lips is 'conduct,' or to the extent that affixing a stamp and distributing information through the mails is 'conduct.'" *Id.* at 59.

⁷⁶*Id.* at 60 – 61. The court was similarly unpersuaded by the FDA's argument that the speech did not deserve First Amendment protection because "of the federal government's extensive power to regulate the pharmaceutical industry through the Pure Food and Drug Act." *Id.* at 60. The FDA relied heavily upon *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447 (1978) and *SEC v. Wall Street Publishing Institute, Inc.*, 851 F.2d. 365 (D.C. Cir. 1998) to argue that there are "[n]umerous examples... of communications that could be regulated without offending the First Amendment," *Ohralik*, 436 U.S. at 456, including the analogous example of securities information, which could be regulated while only triggering "limited First Amendment scrutiny." *Washington Legal Foundation*, 13 F. Supp. 2d. at 60. The court responded "that the argument that a certain subset of speech may be considered completely outside of the First Amendment framework because the speech occurs in an area of extensive government regulation is a proposition whose continuing validity is at best questionable in light of the Supreme Court's most recent commercial speech cases," and in particular, *Liquormart. Id.* (citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996)).

⁷⁷*Washington Legal Foundation*, 13 F. Supp. 2d. at 62 (internal quotation marks omitted) (quoting *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 81 (1983) (Stevens, J., concurring)).

⁷⁸*Id.*

commercial speech rubric.⁷⁹

With the speech classified as commercial speech, the court next considered if the government regulations violated the First Amendment under the four-prong *Central Hudson* test. It was in applying the *Central Hudson* test that the court most clearly broke with the previous tradition of deference to FDA regulations. With respect to the first prong of the test, whether the speech was unlawful, the court rejected as tautological the FDA's claim that "when a manufacturer disseminates information about a drug product that diverges from the treatments included on the label, that manufacturer may be engaged in misbranding, which is illegal."⁸⁰ Instead, the court maintained that such a finding of illegality could only occur under a constitutional regulation, and that it was the very constitutionality of the regulation that was in question.⁸¹ Thus, the court reasoned it needed to proceed to the second part of the first step of the *Central Hudson* test, in which it considered whether the regulated speech in question was misleading.⁸²

Because at this step the *Central Hudson* test only proscribes claims that are inherently misleading,⁸³ the court framed the relevant question as whether "any and all scientific claims about the safety, effectiveness, contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them."⁸⁴ Noting that FDA neither regulated *physician*-initiated requests for information from drug manufacturers nor CME seminars in which there was no manufacturer involvement, the Court denounced the idea that these forms of commercial speech suddenly became inherently misleading when instigated by the manufacturer.⁸⁵ In the court's curt phrase, the "FDA exaggerates its overall place in the universe" by deeming all such speech inherently misleading when it lacks

⁷⁹*Id.* at 64.

⁸⁰*Id.* at 66.

⁸¹*Id.*

⁸²*Id.* at 67.

⁸³*Id.*

⁸⁴*Id.*

⁸⁵*Id.*

FDA approval.⁸⁶

Turning to the second and third prongs of the *Central Hudson* test, the court found that the government did have a substantial interest, however, in regulating the speech and that guidance documents directly advanced that interest. Although it rejected as blatant paternalism the notion that the government had a substantial interest promulgating the guidance regulations because physicians might otherwise misuse the medications,⁸⁷ the court recognized that the government did have a significant interest in providing “manufacturers with ample incentive to get previously unapproved uses on label.”⁸⁸ Recognizing that Congress has “concluded that it benefits the public health to require manufacturers to get all uses approved by the FDA,”⁸⁹ the court determined that the “restrictions on the distribution of enduring materials and involvement with CME do provide an incentive for manufacturers to have previously approved drugs evaluated by the FDA for safety and effectiveness for an off-label use.”⁹⁰

Nonetheless, the court ultimately concluded that the regulations failed the fourth prong of the test: they were “considerably more extensive than necessary” to effectuate the government interest.⁹¹ Rather than restrict the commercial speech simply because it was sponsored by a drug manufacturer, the court proposed the “alternative [of] full, complete, and unambiguous disclosure by the manufacturer,” which would “not only address[] all of the concerns advanced by the FDA, but address[] them more effectively.”⁹² Disclosure would ensure that the physician would not be misled into believing that the manufacturer’s speech carried more weight than it actually did and would still give manufacturers an incentive to seek FDA approval so that they could engage in such activities as mailing their own promotional materials and sponsoring their own seminars for their products.⁹³ In short, the court found disclosure to serve the First Amendment goal of disseminating

⁸⁶*Id.*

⁸⁷*Id.* at 69 – 70.

⁸⁸*Id.* at 69.

⁸⁹*Id.* at 71.

⁹⁰*Id.* at 72.

⁹¹*Id.* at 73.

⁹²*Id.* (citing *Shapero v. Kentucky Bar Ass’n*, 486 U.S. 466, 476 (1988)),

⁹³*Id.* at 73.

more information rather than suppressing it while at the same time furthering the government's interest in ensuring the safety and effectiveness of the drug supply.⁹⁴ As such, the court enjoined the FDA from banning any reprint distributions or CME seminars solely because of the involvement of the manufacturer, so long as the manufacturer's interest in the endeavor is fully disclosed.⁹⁵

B. *Manufacturer – Consumer Commercial Speech: Pearson v. Shalala*

Pearson v. Shalala considered the same commercial speech issues in the context of health claims made by dietary supplement manufacturers to consumers. Again, the court found against the FDA, but the *Pearson* decision was a more measured one, leaving open the possibility of regulation of speech in certain cases. *Pearson* involved a plaintiff manufacturer who wished to include unapproved health claims on a dietary supplement in contravention of the FDA's approval requirements set forth at 21 U.S.C. § 343(r).⁹⁶ Although the FDA had refused to approve the plaintiff's health claims under the significant scientific agreement standard, the plaintiff claimed that the claims were protected under the First Amendment so long as they were true

⁹⁴*Id.* at 73–74.

⁹⁵After this defeat, the FDA filed a motion to amend the judgment in light of the intervening passage of the Food and Drug Modernization Act of 1997. The FDA argued that the Act's provisions superceded two of the three guidance documents that had been the subject of the previous WLF litigation (it argued that only the continuing medical education guidance document) survived the Act, and that the district court should thus modify its injunction accordingly. *Washington Legal Foundation v. Friedman*, 36 F.Supp.2d 16, 18 (D.D.C. 1999). The district court denied the motion to amend its injunction, contending that it applied to the policies underlying the guidance documents and not to the documents themselves. *Id.*

The FDA then appealed this decision to D.C. Court of Appeals, now arguing that the guidelines were merely safe harbors, such that their violation, in itself, would not constitute grounds for the FDA to bring an enforcement proceeding against the violator. *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). Under this weaker understanding of the guidelines, the court of appeals found that there was no actual case or controversy present, *id.* at 336, and thus dismissed the case without reaching the merits of the district court's decision. The battle between the two parties continued when the FDA published a notice in the Federal Register stating its intention to enforce the guidelines as binding law rather than mere safe harbors on the ground that the policies that were the subject of the district court litigation had been wiped clean by the subsequent appellate court litigation. See 65 Fed. Reg. at 14287. The Washington Legal Foundation has currently petitioned the FDA to observe that part of the injunction pertaining to the guidelines regulating continuing medical education that it argues were untouched by the appellate court ruling. See *Washington Legal Foundation, Citizen Petition Regarding Manufacturer Dissemination of Non-Misleading Information Concerning Off-Label Uses of FDA-Approved Products*, May 23, 2001.

⁹⁶*Pearson v. Shalala*, 164 F.3d 650, 654 (1999).

and not misleading.⁹⁷

Finding it to be “undisputed that FDA’s restrictions on appellants’ health claims are evaluated under the commercial speech doctrine”⁹⁸ the court considered whether the health claims, even with a suitable disclaimer stating their tentativeness, were inherently misleading and thus undeserving of First Amendment protection. Much like the *Washington Legal Foundation* court, the *Pearson* court found the contention “almost frivolous” that in most cases disclaimers could not cure the possibility that claims lacking FDA approval might be misleading.⁹⁹ It argued that to assume such claims were inherently misleading would be to ascribe to them such “an awesome impact on consumers” that “it would be as if the consumers were asked to buy something while hypnotized.”¹⁰⁰ The court, however, admitted that the claims could potentially be misleading “because the consumer would have difficulty in independently verifying these [health] claims,” and thus turned to the *Central Hudson* test to assess the constitutionality of the FDA regulations.¹⁰¹

Unlike the *Washington Legal Foundation* court, which found that the regulations failed the second prong of the test to the extent that the government’s interest was that the unregulated speech would mislead physicians, the *Pearson* court recognized that the government did have a substantial interest in the “prevention of consumer fraud.”¹⁰² In addition, the court recognized that the government had a substantial interest in protecting the health of the consumers.¹⁰³ Nonetheless, the court found that neither of these government interests met the requirements of the final two prongs of the *Central Hudson* test. Discussing the government’s interest in consumer health first, the court began from the premise that the government did not allege that the dietary supplements in question were harmful but merely claimed that they were inefficacious. Thus, the court reasoned that consumers could only be harmed by the supplements’ availability in the sense that

⁹⁷*Id.* (“The FDA declined to consider appellants’ suggested alternative of permitting the claim while requiring a corrective disclaimer such as The FDA has determined that the evidence supporting this claim is inconclusive.”)

⁹⁸*Id.* at 655 (citing *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 67 – 68 (1983)).

⁹⁹*Id.* (citing authority).

¹⁰⁰*Id.*

¹⁰¹*Id.*

¹⁰²*Id.* at 656 – 57.

¹⁰³*Id.* at 656.

they might spend their limited health care dollars on ineffective products rather than effective ones.¹⁰⁴ The court dismissed this view of consumer behavior “simplistic,” and further posited that even if the government were worried that consumers would make poor choices in the absence of the regulations, the regulations were only an “indirect route” toward the goal of increasing consumer health, and thus were unjustifiable under the third prong of the *Central Hudson* test.¹⁰⁵

As for the government’s interest in preventing consumer fraud, although the court accepted the notion that the regulatory scheme advanced this interest, it concluded that the scheme was more extensive than was necessary, and thus was unconstitutional under the fourth *Central Hudson* prong.¹⁰⁶ Rejecting the government’s argument that there is no First Amendment preference for disclosure over suppression, the court pointed to a string of commercial speech cases for the proposition that “disclaimers [are] constitutionally preferable to outright suppression.”¹⁰⁷ The court therefore concluded that health claims for dietary supplements were constitutionally protected under the First Amendment so long as they include a disclaimer sufficient to render them non-misleading. In closing, however the court did note that it would still allow the FDA to determine the precise wordings of the disclaimers in the first instance and that it understood that in some cases no disclaimer would be sufficient.¹⁰⁸ Finally, the court also mandated on Fifth Amendment grounds that the FDA precisely define the “significant scientific agreement” standard it uses to determine whether a claim should be approved.¹⁰⁹

Part IV: Analysis of *Washington Legal Foundation* and *Pearson*

¹⁰⁴*Id.*

¹⁰⁵*Id.*

¹⁰⁶*Id.* at 656 – 57.

¹⁰⁷*Id.* at 657.

¹⁰⁸*Id.* at 659.

¹⁰⁹*Id.* at 660.

Washington Legal Foundation and *Pearson* represent a recent shift in food and drug commercial speech jurisprudence toward greater protection of manufacturer claims. Despite the FDA's adamant insistence that its regulations are not subject to the strictures of the First Amendment, the *WLF* and *Pearson* Courts have moved toward greater protection for commercial speech. Yet the doctrine is far from settled,¹¹⁰ and further inquiries must be made into the precise scope of protection that commercial drug speech deserves. As such, the cases leave unaddressed some questions about the scope of this protection and invite further debate about questions that the cases did address. Perhaps appropriately, given the relative savvy of physicians as compared to consumers, *Washington Legal Foundation* takes a less forgiving stance toward policies that could be considered paternalistic; yet, the decision's failure to acknowledge any government interest in ensuring that physicians do not use erroneous or biased information seems questionable. While the court was correct to find this speech not to be inherently misleading, there still may be particular examples of such speech that are misleading.

Similarly, although *Pearson* allows for the possibility that some health claims may be so misleading that no disclaimer could cure them, it also makes the questionable assumption that in most cases consumers will be able to evaluate the validity of those claims. Another point of puzzlement is the different weights the two courts ascribe to the public interest in using these products properly: while the *Washington Legal Foundation* Court rejects such concerns as paternalistic, the *Pearson* gives them at least some weight. In the remainder of this paper I argue that although the FDA's absolutist stance against First Amendment protection for commercial speech is untenable, the *Pearson* and *WLF* Courts leave us unsure about the precise boundaries of the protection deserved by the speech.

A.

¹¹⁰See *Washington Legal Foundation v. Henney*, 128 F.Supp.2d 11, 15 (“After six years’ worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved, and the country’s drug manufacturers are still without clear guidance as to their permissible conduct.”) (D.D.C. 2000)

Although *Washington Legal Foundation* constitutes a greater departure than does *Pearson* from preexisting food and drug law speech doctrine, its wholesale rejection of any government interest in ensuring that physicians receive and properly use correct information about the drugs they prescribe may yet be defensible precisely because it is physicians who are the intended targets of the speech. Nevertheless, the district court’s decision dispenses too quickly with the government’s proposed interest. The *Washington Legal Foundation* court simply assumed that any such government motive must be discarded as wholly paternalistic. In lofty language, the court refers to the “one fixed principle in the commercial speech arena” that “a State’s paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it.”¹¹¹ It is, however, a fine line between paternalism and public safety. For although it may be the case that restrictions on nonmisleading speech have no place in our current First Amendment commercial speech jurisprudence, it is far from clear that the manufacturer-sponsored reprints and CME seminars are actually always nonmisleading.

Indeed, the *Washington Legal Foundation* court only determined that the speech in question was not “inherently misleading,” leaving open the possibility that the speech might be still be potentially misleading in some cases.¹¹² Although the court never addressed the possibility explicitly, it made much of the fact that FDA did not regulate reprint distributions from manufacturers that were sent at the physician’s request. This one-way regulation appeared to have posed a logical conundrum to the court: how could information that was not potentially misleading if requested by the physician suddenly become misleading if sent by the manufacturer on its own?

While the transformation is at least somewhat puzzling, it is also not wholly inexplicable. First, even if one

¹¹¹ *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 69 – 70 (D.D.C. 1998) (internal quotation marks omitted) (quoting 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497 (1996)).

¹¹² *Id.* at 69.

grants the premise that reprints would be equally misleading to physicians who requested them as well as to those who did not, the FDA may have had prudential reasons for not “proscrib[ing] dissemination under all circumstances.”¹¹³ Although in some areas of medicine off-label uses predominate,¹¹⁴ there are presumably some off-label uses that are on the whole more dangerous than on-label uses precisely because the latter have been tested more extensively. Nevertheless, the FDA makes no effort to regulate physician use of drugs for off-label purposes because it stated that it does not wish to use its enforcement powers to compromise the physician’s autonomy in that way.¹¹⁵ Analogously, the FDA may not wish to compromise the autonomy of the physician with respect to medical journal reprints. Indeed, if the FDA is content to allow physicians to actually prescribe drugs for off-label uses, then surely it is not unreasonable to permit the physicians to request information about these off-label uses.

Second, it may be reasonable to assume that physicians who request their own information from the company may have some heightened awareness of the considerations surrounding the drug’s off-label uses. Compared to the physician who receives the materials unbidden, the instigating physician may already have some sense of the off-label uses of the drug from conversations with colleagues or from having read other articles discussing the drug. In these situations, the FDA’s requirement that the reprinted material primarily focus on the approved uses for the drug may not be as germane. In contrast, the physician who hears about the off-label use for the first time through an unrequested reprint sent by the manufacturer may need the information about the approved uses of the drug to make an informed decision about the manner in which she would prescribe it.¹¹⁶

¹¹³*Id.*

¹¹⁴*See, e.g.,* Washington Legal Foundation, *Citizen Petition Regarding Dissemination of Non-Misleading Information Concerning Off-Label Uses of FDA-Approved Products*, *4 - *5, (May 23, 2001).

¹¹⁵*See* Washington Legal Foundation v. Friedman, 13 F. Supp. 2d. 51, 55 (1998)

¹¹⁶Note further that the court’s analysis assumes that only experienced physicians will prescribe drugs for off-label uses. To the extent that a physician is prescribing drugs outside his specialty, the importance of FDA regulations increases.

But although these considerations perhaps delineate a lower bound for First Amendment protections, they also show the difficulty of articulating a workable test for determining when safety concerns should trump the speech interest in question. That is, while the above analysis suggests that at a minimum manufacturers should be allowed to send materials without fear of FDA reprisal to doctors who request them (a relatively uncontroversial position the FDA itself does not challenge), it also suggests that in some areas of medicine (namely those in which off-label uses are rare) there may be greater risks associated with off-label uses, rendering the speech interests in them less compelling. But how are courts to know whether there is a particular risk associated with a particular off-label use? In the end, the *Washington Legal Foundation* solution of requiring disclosure, and ultimately letting physicians decide what constitutes a safe use seems for the most part reasonable. But the court's refusal to find any government interest in ensuring safety suggests that it missed an opportunity to set out guidelines detailing when a speech interest might be defeated by a greater interest in safety.

Another consideration not addressed by the court concerns the role and rights of the patient with respect to the physician's choice. Patients have little to no knowledge about whether the drugs their physicians prescribe are being used for on-label or off-label uses. Patients, however, may have a significant interest in knowing that the drugs they are consuming are being used in a FDA-approved manner on the assumption that such uses are safer than off-label uses. If lifting the commercial speech regulations that prevent promotion of these off-labels uses is likely to encourage doctors to prescribe those uses, then simply requiring manufacturer disclosure to physicians will not solve the problem of *patients* being exposed to more off-label uses than they might wish to be. Additionally, the court seemed to give no weight at all to the FDA's determination that the public health would be best served by a regime in which mere disclosure would be insufficient to allow

a manufacturer to promote off-label uses.¹¹⁷

In the end, though, these concerns may ultimately be subsidiary to the First Amendment interests implicated by the manufacturer, for it is indisputable that recent cases like *Liquormart* stress the importance of disclosure over suppression and reject paternalistically-motivated restrictions on speech. What the *Washington Legal Foundation* court failed to do, however, was probe more deeply into the government's interest in regulating these off-label uses. Although it is likely that the analysis would have come out the same way¹¹⁸ in light of the great importance of these sorts of First Amendment values, commercial speech jurisprudence would have been better served with a more detailed analysis of the issues involved.

B.

Ostensibly, *Pearson* is the more measured decision of the two, given that it recognized a government interest in promoting the health of citizens and that it did not hold that disclaimers would always be sufficient to make an otherwise misleading label non-misleading. Nevertheless, the nuanced aspects of the decision are undercut somewhat by its questionable assumptions about human nature and the market for dietary supplements. Thus, while the opinion is admirable for attempting to¹¹⁹ carve out exceptions to the FDA's monolithic approach to labeling, its relatively cursory treatment of those issues suggests that factors that would separate a sufficient disclaimer from an insufficient one have not completely been satisfactorily articulated.

¹¹⁷See Gilhooley, *supra* note 44, at 837.

¹¹⁸This seems particularly likely given that physicians are not ordinary consumers for whom increased regulation might be appropriate, but highly skilled professionals who possess a great deal of expertise about the drugs in question. *But see supra* note 116.

¹¹⁹The FDA has continued to contest the decision, culminating in *Pearson v. Thompson*, 2001 WL 502115 (denying FDA's motion to reconsider the district court decision, *Pearson v. Shalala*, 130 F.Supp.2d. 105 (D.D.C. 2001) which enjoined the FDA to promulgate suitable warnings for the plaintiff's product) (D.D.C. 2001). In this latest development in the *Pearson* saga, the court reiterated that the FDA may only impose an outright ban on a supplement claim where there evidence against the claim is qualitatively weaker than the evidence in favor of it. *Id.* at 12. The court further noted that the mere absence of evidence in support of a claim is insufficient to count as evidence against the claim.

Beginning with *Pearson*'s assumptions regarding human nature, the court contended that one would need to believe that consumers would essentially be "hypnotized" by health claims lacking significant scientific agreement to argue that a disclaimer would be insufficient to cure its misleadingness.¹²⁰ Although there is at least an intuitive appeal to the idea that any doubt about the efficacy of a dietary supplement could be eliminated by the inclusion of an appropriate disclaimer, ultimately such a view would appear to be tinged with a sort of Panglossian optimism. Consumers who consider purchasing dietary supplements may not resemble the model of the rational economic actor that seems to underlie the *Pearson* court's assertions.

These disclaimers are problematic because even consumers who are not sick may have trouble verifying independently the health claims attributed to the dietary supplement. This effect may be exacerbated by the fact that many potential consumers of dietary supplements are sick or are becoming sick. These consumers, anxious to have their ills alleviated, may pay less attention to a disclaimer accompanying an attractive health claim. Studies show that a significant portion of the population already believe that dietary supplements can generally help people with... illnesses.¹²¹ Presumably, these individuals, who already trust in the curative power of supplements, may be even more inclined to purchase the supplement regardless of disclaimers when they become sick.

The *Pearson* court did not appear to attach much significance to the harms that might be caused by

¹²⁰*Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999).

¹²¹National Public Radio/Kaiser Family Foundation/Kennedy School of Government Survey on Americans and Dietary Supplements, at question 8 (1999) (visited Mar. 29, 1999), <www.npr.org> [hereinafter NPR Poll]. Forty- nine percent of those surveyed believed that supplements could help them with the flu, 61% with a cold, 35% with cancer, 16% with AIDS, 53% with arthritis, and 52% with depression. *Id.*

consumers purchasing dietary supplements as a result of the health claims (albeit disclaimed ones) that were included on the label. Although it seems intuitive that a consumer that spends money on ineffective dietary supplements will have less money to spend on effective health treatment, the court dismissed this phenomenon, terming it “dubious” and “simplistic.” Contrary to the court’s assertions, there is at least some evidence that consumers do use dietary supplements as a replacement for visits to their doctors. Consumers have been known to use supplements to treat such illnesses as “high blood pressure, high cholesterol, diabetes, and... cancer.”¹²² Leaving aside the fact that there is no compelling evidence that dietary supplements have any effect upon these illnesses, the more disturbing implication of this evidence is that consumers may believe that they are getting treatment through the supplements for their problems when they in fact are not. To the extent that this is correct, it is irrelevant that the dietary supplements are innocuous in and of themselves because consumers may be misled into thinking that they will not need to seek professional treatment because they have access to dietary supplements.

Finally, when the *Pearson* decision is read against the backdrop of *Washington Legal Foundation*, it is unclear how much weight courts will give to the public interest in making sure that the products are used properly. *Pearson* still recognizes a government interest along these lines (even if it may only be dispositive rarely); *Washington Legal Foundation*, as discussed above, rejects such this interest as illegitimately paternalistic. Perhaps the distinction can turn on the respective audience in each case—consumers in the former and doctors in the latter. Yet, for the reasons described above, there still may be legitimate safety concerns even when doctors are the audience for the commercial speech. Until the disparate treatment of the safety interests in the two cases are reconciled, we must wait for the final structure of the drug speech doctrine.

¹²²Khatcheressian, *supra* note 64, at 631 (citing National Public Radio (Morning Edition broadcast, Mar. 30, 1999) (visited Apr. 1, 1999) <www.npr.org/programs/morning/dietsupplements/html> (interviewing consumer who, against the advice of physicians, is using dietary supplements to treat high blood pressure, cholesterol, and borderline diabetes)); *see also* Max J. Coppes, *Alternative Therapies for the Treatment of Childhood Cancer*, NEW ENG. J. MED. Sept. 17, 1998, at 846- 47 (discussing two child cancer patients whose parents opted to treat them with herbal compounds, in one case Matol Biomune OSF Plus (alleged to create a synergistic effect on the immune system, resulting in the elevation of natural killer cell activity and promoted as beneficial for the treatment of a variety of cancers and other diseases), and shark cartilage in the other)).

Thus, while the FDA's reluctance to permit disclaimers of any kind is misguided, the *Pearson's* court quick dismissal of possibly countervailing concerns regarding consumer safety was also unhelpful. Although the court was correct to refuse to draft the disclaimers itself, it could have done more to articulate what types of biases consumers might have when they consider purchasing these supplements, so as to provide the FDA with more guidance as to what would constitute a reasonable disclaimer.

Conclusion

While it is clear that the constitutional status of commercial drug speech is not yet settled, there has been an undeniable trend in recent years in the direction of greater protection. Clearly, the FDA has not embraced the early changes of this new regime, and it remains to be seen how successful it will be in resisting a further expansion of the doctrine. For their part, having begun to give greater weight to speech interests, the courts must now refine the doctrine to give parties a clearer picture of which practices will be protected and which will not. This will require a careful weighing of the interests involved so as to avoid paternalism while at the same time recognizing the special risks inherent in unsafe pharmaceuticals and dietary supplements. In a sense, the previous regime of little to no first amendment protection for commercial speech was a far simpler world. *Washington Legal Foundation* and *Pearson* provide a signal that courts have finally begun to take up the complexities of the issue. Now it just remains to be seen how they ultimately resolve them.